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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	10/019,848	KRATKY ET AL.	
	Examiner	Art Unit	
	Traviss C McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 24-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Amendment filed August 25, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 10 and 12 have been amended.

Claim 23 has been canceled.

Remarks drawn to rejections of Office Action mailed June 2, 2003 include:

Specification objection: which has been overcome by applicant's amendments and arguments and has been withdrawn.

Claim objections: which have been overcome by applicants' amendments and have been withdrawn.

112 2nd paragraph rejections: have been overcome in part by applicants' amendments and have been withdrawn in part.

An action on the merits of claims 1-22 and 24-39 is contained herein below.

The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-22 and 24-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite wherein the claim recites "a composition for an infant formula comprising a protein source which has a low threonine content and comprising...". It is unclear what is intended by "a protein source". The recitation of "a protein source" is confusing in the instant claims. It appears applicants intend the composition to comprise a protein, not a protein source, as a protein source is, for example, fish, meat, cheese, etc. Removing "source" would be seen to obviate the rejection. Applicants argue on page 8 of their response that "the specification discloses that the composition comprises a lipid source, a carbohydrate source and a protein source." A specific example of a protein source according to an embodiment of the present invention is further defined, for example, on page 5 at lines 6-8 where the protein source can include hydrolyzed sweet whey, arginine, tyrosine, and histidine in specified amounts". First this is not seen as a clear and exact definition, as "the protein source can include" is not definitive. Something which is defined in a way which does not clearly sets forth that which is intended, but rather which is defined by "this can include something" is indefinite. Moreover, in the examination process, it is proper to use the specification to interpret what applicant intends by a word or phrase recited in the claims, but it is **not** proper to read these limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen,* 30 F. 3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).

Additionally, claim 1 is indefinite as it is unclear if the following components, the whey, free arginine, free histidine, etc. in the claim are intended as additional agents incorporated in the composition or if these components are defining the protein which has a low threonine content. Applicants argue that the specification defines the composition on page 2, lines 11-17 as a composition containing 4 items: 1) an acid whey protein or modified sweet whet protein; 2) free

arginine; 3) free histidine; and 4) free tyrosine or tryptophan. However, the claim as written reads as "a composition for an infant formula comprising a protein source which has a low threonine content and comprising: ... ", which reads as though there is: 1) a protein source which has a low threonine content; 2) an acid whey protein or modified sweet whet protein; 3) free arginine; 4) free histidine; and 5) free tyrosine or tryptophan. Additionally, claim 18 is drawn to a method of producing an infant formula comprising "blending 1) whey protein and 2) casein protein with 3) free arginine, 4) free histidine, and 5) free tyrosine or tryptophan, thus the method claim is drawn to 5 active agents. Moreover, in the examination process, it is proper to use the specification to interpret what applicant intends by a word or phrase recited in the claims, but it is **not** proper to read these limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen,* 30 F. 3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).

The term "**low** threonine content" in claim 1 for example, is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The term "low" is indefinite in all claims in which it occurs without defining what is intended by "low". Applicants argue that low is defined in the specification, for example, on page 2 at lines 34-35 as, "the threonine content can be less than about 8g/16gN, more preferably less than about 6g/16gN". Defining something as "this can be less than about that" is not a definition of anything, but an example of what it might be, as nothing is necessarily delimited by the phrase "can be less than about" nor is anything defined by the phrase. Moreover, in the examination process, it is proper to use the specification to interpret what applicant intends by a word or phrase recited in the claims, but it

is **not** proper to read these limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen,* 30 F. 3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).

The term "**tryptophan rich** milk protein" in claim 1 for example, is a relative term which renders the claim indefinite. The term "tryptophan rich" is not defined by the claim, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The term "tryptophan rich" is indefinite in all claims in which it occurs without defining what is intended by said term. Applicants argued that the specification discloses what is intended by "tryptophan rich", however, as set forth supra, applicant's definition if the specification does not limit anything, but merely presents a few variables which are preferred by applicants. Moreover, in the examination process, it is proper to use the specification to interpret what applicant intends by a word or phrase recited in the claims, but it is **not** proper to read these limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen,* 30 F. 3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).

The term "**substantially free**" in claim 6 for example, is a relative term which renders the claim indefinite. The term "substantially free" is not defined by the claim, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The term "substantially free" is indefinite in all claims in which it occurs without defining what is intended by said term. Applicants argue that "substantially free of lactose" for example is defined in the specification on page 3, lines 29-31, wherein the specification reads: "the whey protein is substantially free of lactose. This has the advantage that the infant formula has reduced levels of lysine blockage. Preferably, the level of lysine blockage is less than 10%". This is not seen as a

proper definition of "substantially free". Moreover, in the examination process, it is proper to use the specification to interpret what applicant intends by a word or phrase recited in the claims, but it is **not** proper to read these limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen,* 30 F. 3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).

Claim 11 is indefinite wherein the claim provides limitations wherein the composition of claim 1 "comprises a lipid source and a carbohydrate source". It is unclear if applicant intends to add compounds which are sources for making lipids and carbohydrates, or if they intend to add lipids and carbohydrates. Applicants argue that these terms are defined in the specification, however, in the examination process, it is proper to use the specification to interpret what applicant intends by a word or phrase recited in the claims, but it is **not** proper to read these limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen,* 30 F. 3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994). Moreover, it is the recitation of "source" which is confusing. As set forth supra, removing "source" would be seen to obviate the rejection.

Without quantitative designations supported by the disclosure to render definite the terms "low", "rich", etc., these claims are still seen to be indefinite for reasons of record.

All claims which depend from an indefinite claim are also indefinite. ***Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).***

Claim Rejections - 35 USC § 103

The rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over Harzer et al. (EPO 418 593 A2) is maintained for reasons of record.

Claim 18 is drawn to a method of producing an infant formula comprising blending whey protein and casein protein with free arginine, free histidine, and any of free tyrosine, free tryptophan, or tryptophan rich milk protein, and then homogenizing the blended mixture.

Harzer et al. disclose a method of making an infant formula comprising the steps of stirring with an intensive stirrer protein concentrates and L-amino acids until the mixture is homogenous and then carrying out homogenization (page 7, 2nd and 3rd paragraphs). Harzer et al. then disclose that the intact proteins can be replaced with hydrolyzed proteins, such as whey hydrolysates, casein hydrolysates, etc. (page 8, 2nd paragraph). The amino acids disclosed to be added to the compositions include histidine, isoleucine, leucine, valine, and tyrosine to name a few (see the compositions in examples). Additionally, they are taught to be added in their free form (page 3, 4th full paragraph). What is not taught is to specifically add free arginine, although Harzer et al. clearly state that "in cases where it is not possible, or where it is possible only with difficulty, to achieve the desired amino acid composition by mixing different ... proteins and/or peptides, then one can add amino acids in the free form for the purpose of producing these amino acid mixtures which contain the indicated amino acids in the desired range (page 3, bottom paragraph), then teaches that arginine is required in the composition an amount of 1.99-2.69g/100g total amino acids.

When determining the patentability of process of making claims, the determination is based on the inventiveness of the process steps themselves, and not necessarily on the

compositions/compounds of the process (SEE ***Ex parte Ochiai (BPAI 1992) 24 PQ2d 1265).*** In the instant case, the process of blending the mixture with subsequent homogenization is known in the art. One of ordinary skill in the art would recognize that adding another or a different amino acid would not effect the known process to obtain an improved process, but merely provide an end product which has slightly different properties which is based solely on the "ingredients" of the process, not based on the methodological steps. The instant method is not seen as an improvement over the prior art, as all methodological steps are correlative to those of the prior art.

Applicants argue that the whey protein is selected to provide a lower threonine content that is closer to milk. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the various specified whey proteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, applicants state that Harzer supplements the protein in an amount from 3.62-4.90g/100g the total amino acids. However, this is a misrepresentation of Harzer, as the 3.62-4.90g/100g is the amino acid analysis of the composition wherein the threonine is a product of the whey protein/sodium caseinate, see composition portions of the examples and corresponding amino acid analysis wherein there is no threonine added in any of the compositions. Moreover, the amount dictated by Harzer is seen to be a "low threonine content". As set forth supra, the steps of blending proteins with free amino acids followed by homogenization is known in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623

Traviss C. McIntosh III
October 28, 2003